UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE

LITIGATION

MDL NO. 1456 CIVIL ACTION NO. 01-12257-PBS SUBCATEGORY NO. 08-11200-PBS

THIS DOCUMENT RELATES TO:

UNITED STATES ex rel. LINNETTE) SUN and GREG HAMILTON, RELATORS) v. BAXTER HEALTHCARE CORPORATION

MEMORANDUM AND ORDER

August 7, 2012

Saris, U.S.D.J.

INTRODUCTION I.

In this qui tam action under the federal False Claims Act, Relators Linette Sun and Greg Hamilton ("Relators") claim, among other things, that Baxter Healthcare Corporation ("Baxter") fraudulently inflated the prices of the drugs, Recombinate and Advate, and caused overpayments by Medicaid and Medicare. On January 26, 2012, this Court allowed Baxter's motion for partial¹

¹ The other counts related to relator Linnette Sun's retaliation and employment discrimination claims were not challenged.

summary judgment. See In re Pharm. Indus. Average Wholesale

Price Litiq., No. 01-12257-PBS, 2012 WL 366599 (D. Mass. Jan. 26, 2012). Baxter's partial motion for summary judgment was allowed based upon the broad release that qui tam relator Ven-A-Care of the Florida Keys ("Ven-A-Care"), with the government's consent, provided to Baxter in connection with Ven-A-Care's settlement of similar claims against Baxter involving Recombinate and other drugs.

Relators have moved for reconsideration pursuant to Fed. R. Civ. P. 59(e). They argue they are entitled to a hearing regarding the fairness, adequacy, and reasonableness of the settlement agreement between Ven-A-Care and Baxter. They also seek a share of the proceeds of that settlement. Neither of these arguments was raised during the summary judgment proceeding, though they could have been. Both the government and Ven-A-Care have been allowed to weigh in on the novel procedural issues raised by the case. The motion for reconsideration is denied without prejudice.

II. DISCUSSION

A. Standard of Review

There are generally only four recognized grounds upon which the Court can grant a Rule 59(e) motion: (1) manifest errors of law or fact, (2) newly discovered or previously unavailable evidence, (3) manifest injustice, and (4) an intervening change in controlling law. See Marie v. Allied Home Mortgage Corp., 402 F.3d 1, 7 n. 2 (1st Cir. 2005) (citing 11 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2810.1 (2d ed. 1995)).

B. Settlement as "Alternate Remedy"

Under the False Claims Act, a person may bring an action "in the name of the Government" seeking civil remedies for fraud against the United States. 31 U.S.C. § 3730(b)(1). "The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." Id. In addition,

[n]otwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section.

31 U.S.C. § 3730(c)(5) (emphasis added). Thus, relators do not lose their rights under the False Claims Act when the government pursues an alternate remedy with respect to their claims.

If the government pursues an alternate remedy, one of the rights to which the relator is entitled is the right to obtain a share "of the proceeds of the action or settlement of the claim." 31 U.S.C. § 3730(d)(1); see U.S. ex rel. Bledsoe v. Community <u>Health Systems</u>, <u>Inc.</u>, 342 F.3d 634, 649 (6th Cir. 2003). addition, if the alternate remedy is a settlement, the relator has a right to have "the court determine[], after a hearing, [whether] the proposed settlement is fair, adequate, and reasonable under the all the circumstances." 31 U.S.C. § 3730(c)(2)(B); see United States ex rel. LaCorte v. Wagner, 185 F.3d 188, 191 (4th Cir. 1999). Relators argue the Settlement Agreement and Release executed by Baxter and Ven-A-Care, and to which the government consented, constitutes an "alternate remedy" for the claims it brought against Baxter. 31 U.S.C. § 3730(c)(5). As a result, Relators maintain, they are entitled to a hearing regarding the fairness of the settlement and to a share of the resulting proceeds.

As background, after Relators brought their action, the government consented under 31 U.S.C. § 3730(b)(1) to the dismissal with prejudice of similar claims that Ven-A-Care had

previously made against Baxter on behalf of the government. government's consent was provided "pursuant to, and as limited by, the Settlement Agreement and Release" between Ven-A-Care and Baxter. Consent of the United States of America to the Relator's Dismissal with Prejudice of Claims Pursuant to 31 U.S.C. § 3730(b)(1), Civil Action No. 1:01-cv-12257-PBS (Oct. 7, 2011) (Master Doc. No. 7831-1). In exchange for the payment of \$25,000,000, the release "fully and finally releases, acquits, and forever discharges" Baxter from any "claim, action, suit, demand, right, cause of action, liability, judgment, damage, or proceeding . . . which has been asserted, could have been asserted, or could be asserted in the future . . . for or arising from any of the Covered Conduct " Settlement Agreement and Release at ¶ III.7, Civil Action No. 1:01-cv-12257-PBS (Oct. 7, 2011) (Master Doc. No. 7832-1). The agreement defines the term "Covered Conduct" to include the submission of false claims to Medicaid and Medicare and the reporting of false prices for "any and all drugs manufactured, marketed and/or sold by or on behalf of any Baxter Party " Id. at ¶ II.E (emphasis added).

Although this broad release language extinguished Relators' claims regarding Recombinate and Advate, <u>see In re Pharm. Indus.</u>

<u>Average Wholesale Price Litig.</u>, No. 01-12257-PBS, 2012 WL 366599

(D. Mass. Jan. 26, 2012), no one notified the court nor Relators Sun and Hamilton that the settlement effectively extinguished their claims.² The government, which had not intervened in the action, contends that it did not understand or intend that the broad release language cover drugs not asserted in the Ven-A-Care complaint. See Statement of the United States in Response to the Electronic Order of February 24, 2012 (Doc. No. 166) at 1-2.

Relators argue the government pursued an "alternate remedy" to the False Claims Act claims they brought against Baxter by consenting to the settlement between Ven-A-Care and Baxter. 31 U.S.C. § 3730(c)(5). In U.S. ex rel. Bledsoe v. Community Health Systems, Inc., 342 F.3d 634 (6th Cir. 2003), the Sixth Circuit held that "'alternate remedy' refers to the government's pursuit of any alternative to intervening in a relator's qui tam action . . . [A] settlement pursued by the government in lieu of intervening in a qui tam action asserting the same FCA claims constitutes an 'alternate remedy' for purposes of 31 U.S.C. § 3730(c)(5)." Id. at 647-49. The Court further observed that it was

² The settlement was docketed on the multi-district litigation docket, which at that point had over 7,000 docket entries. It was not separately filed in the subcategory applicable to Relators. Nonetheless, Relators received actual notice of the settlement.

not alone in our view of a § 3730(c)(5) "alternate remedy." The Ninth Circuit has held that an administrative suspension or debarment proceeding pursued by the government, and a settlement agreement arising therefrom, constituted an "alternate remedy" within the meaning of § 3730(c)(5), even though the government had not intervened in a qui tam suit alleging the conduct contemplated in the settlement. United States ex rel. Barajas v. United States, 258 F.3d 1004, 1010-13 (9th Cir. 2001). Similarly, the Fourth Circuit appears to view § 3730(c)(5) as protecting a relator's rights when the government pursues an alternative to intervening in the relator's qui tam action. [See United States ex rel. LaCorte v. Wagner, 185 F.3d 188, 191 (4th Cir. 1999)].

Id. at 649. The Sixth Circuit explained that if the government's extinguishing of a relator's claims by reaching a separate settlement with the defendant were not considered an "alternate remedy" under 31 U.S.C. § 3730(c)(5), then

the government could decline to intervene in a qui tam suit, then settle that suit's claims separately and deny the relator his or her share of the settlement proceeds simply because the government had not formally intervened in the qui tam action. Consequently, the government would frequently carry the incentive to decline to intervene in an action and, having been apprised of possible FCA violations by a private citizen, to independently pursue an investigation of the alleged FCA violator(s). Such a result would not further Congress' legislative intent that the government and private citizens collaborate in battling fraudulent claims, and it would impede, not further, Congress' legislative intent to encourage private citizens to file qui tam suits.

<u>Id.</u> at 649. Thus, to encourage private citizens to file qui tam suits, the False Claims Act provides relators with the right to

claim a share of the proceeds, and a hearing regarding the fairness, of the government's settlement of their claims.

Here, the government's consent to the dismissal of Ven-A-Care's claims against Baxter pursuant to the broad Settlement Agreement and Release, which, albeit unwittingly, extinguished Relators' claims, constitutes an "alternate remedy" under 31 U.S.C. § 3730(c)(5). The government effectively settled Relators' claims by approving the settlement between Ven-A-Care and Baxter, and such a separate settlement constitutes an "alternate remedy." See Bledsoe, 342 F.3d at 647-49; Barajas, 258 F.3d at 1010-13.

The government maintains it "believed its consent [to the Settlement Agreement and Release between Ven-A-Care and Baxter] would be effective only with respect to the claims pled by Ven-A-Care -- and not those pled by Sun and Hamilton -- based on the plain language and structure of the False Claims Act." Statement of the United States in Response to the Electronic Order of February 24, 2012 (Doc. No. 166) at 1-2. While the government's position is unclear, it appears to be arguing that it could not have settled any claims against Baxter not contained in the Ven-A-Care case. This is partly true, as the government cannot settle a claim brought by another relator without a hearing on

the fairness of the settlement. However, contrary to the government's argument, the statute does not require the government to intervene in a relator's action in order to settle it with an "alternate remedy." See Bledsoe, 342 F.3d at 647-49 (rejecting the government's claim that "Congress intended the 'alternate remedy' provision to apply only when the government has intervened in the action."); Barajas, 258 F.3d at 1006; cf. <u>U.S. ex rel. Schweizer v. Oce N.V.</u>, 677 F.3d 1228, 1233 (D.C. Cir. 2012) ("Intervention is necessary 'only if the government wishes to 'proceed with the action Here, the government did not seek to proceed with the qui tam portion of the case; it sought to end it. It follows that the government did not have to intervene before filing its motion [to dismiss the relator's qui tam claims after reaching a settlement agreement with the defendant]."). The government has not sought to rescind, or withdraw its consent from, the Settlement Agreement and Release between Ven-A-Care and Baxter now that the Court has construed the meaning of the release contrary to its understanding.

Baxter makes several arguments opposing Relators' motion for reconsideration. Although Baxter recognizes that relators "are entitled to notice of settlement of their <u>own</u> False Claims Act case. <u>See</u> 31 U.S.C. § 3730(c)(2)(B)," it contends that "Relators

cite no authority for the proposition that a relator in one FCA case has the right to notice and a hearing about a <u>different</u> FCA case." Baxter Opp. at 5 (emphasis in original). It is true that unlike the situation here, in <u>Bledsoe</u> and <u>Barajas</u> the separate settlement was not a part of a different False Claims Act case. However, these cases stand for the proposition that when the government has not intervened in a relator's case, its separate settlement of the relator's claim constitutes an "alternate remedy" under 31 U.S.C. § 3730(c)(5) and therefore the court must hold a hearing regarding the settlement.

Baxter also argues Relators' request to be heard regarding
Baxter's settlement with Ven-A-Care comes too late because
Relators had actual notice of the settlement and prior
opportunities to object to, or request a hearing regarding, the
settlement.³ Of course, it would have been preferable
(particularly with respect to Recombinate) if the issue had been
vetted at the summary judgment hearing, but Relators
(consistently with the government) believed that the settlement
and release did not apply to their claims at that point. But
once I construed the release, they timely raised 31 U.S.C. §

³ As clarified in the Declaration of Mark Kleiman (Doc. No. 176), Relators did have actual notice of the Ven-A-Care settlement before the court approved it.

3730(c)(2)(B), which applies when the government pursues its claim through any alternate remedy.

Finally, Baxter maintains that even if 31 U.S.C. § 3730(c)(2)(B) could potentially apply (because the government pursued "any alternate remedy" under 31 U.S.C. § 3730(c)(5) through its approval of the Ven-A-Care settlement), that provision is not relevant here because it applies only when the government has settled a relator's action and not when the government merely settles a relator's claim asserted on the government's behalf. According to the statute, "[t]he Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances." U.S.C. § 3730(c)(2)(B) (emphasis added). Baxter argues the Ven-A-Care settlement did not settle Relators' "action," and thus § 3730(c)(2)(B) does not apply. However, the settlement extinguished all of Relators' pending federal False Claims Act pricing claims and thus effectively settled that aspect of their action. Moreover, Baxter has not cited any cases limiting the application of 31 U.S.C. § 3730(c)(2)(B) when the government settles at least one but not all of a relator's claims; such a

limitation would be inconsistent with "Congress' legislative intent to encourage private citizens to file qui tam suits." Bledsoe, 342 F.3d at 649.

C. Procedural Issue

The difficult procedural question is what to do next. Relators have moved "pursuant to Federal Rule of Civil Procedure 59(e), this Court to reconsider and vacate its January 26, 2012 Memorandum Opinion and Order allowing Baxter Healthcare Corporation's ("Baxter") motion for partial summary judgment dismissing the Relators' pending federal False Claims Act claims." Relators' Combined Motion to Reconsider and Memorandum in Support (Doc. No. 159) at 1. Relators' primary argument appears to be that "the Court's partial summary judgment ruling failed to consider, and thus violated, the express statutory rights of the Relators in this case to notice and a hearing on any settlement of their case, and a right to their share of the settlement proceeds." Id. at 2. Pressing an argument that the Court erred in granting Baxter's motion for partial summary judgment on the meaning of the release does not lead to the requested relief. Instead, it is the Court's allowance of Baxter's motion for partial summary judgment and the consequent extinguishing of Relators' claims that provides Relators with the right they claim to a hearing regarding the fairness of the Ven-A-Care settlement and a share of the proceeds. See 31 U.S.C. § 3730(c)(2)(B). While no cases are directly on point to assist in sorting out this procedural pretzel, at least one case suggests that Relators should move to reopen the judgment in the Ven-A-Care case to obtain a fairness hearing with respect to the Ven-A-Care settlement. Cf. LaCorte v. Wagner, 185 F.3d 188, 191 (4th Cir. 1999) ("Indeed, an original qui tam plaintiff [can] vindicate his rights when the government pursues an alternate remedy . . . If the relator believes that the government acted improperly in procuring a settlement, then he may return to the court which had jurisdiction over the settlement and move to reopen the judgment under Fed. R. Civ. P. 60(b)(6).").

At that hearing, the court will address whether the settlement is fair in light of its release of Relators' claims. Ven-A-Care alleges the court lacks subject matter jurisdiction over Relators' Recombinate and Advate claims under the first-to-file requirement. I should add that it is not clear from the most recent filings that Relators are pressing for a share of the settlement related to their Recombinate, as opposed to their Advate, claim. See Doc. No. 159. However, with respect to Advate, the Court will have to determine whether it has jurisdiction.

III. ORDER

Relators' Combined Motion to Reconsider (Doc. No. 159) is

DENIED without prejudice. Plaintiffs may file a motion to reopen
the judgment under Fed. R. Civ. P. 60(b)(6) in <u>United States of</u>

America ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter

Healthcare Corporation and Baxter International, Inc., Civil

Action No. 01-CV-12257-PBS, Subcategory No. 06-11337.

/s/ PATTI B. SARIS
PATTI B. SARIS
UNITED STATES DISTRICT JUDGE